

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

IN RE BEXTRA AND CELEBREX  
MARKETING SALES PRACTICES AND  
PRODUCT LIABILITY LITIGATION

Civil Case No.: 08-cv-00402

Related Case Number M:05-cv-01699-CRB  
MDL No. 1699  
Pending in the Northern District of California, San  
Francisco Division

**REPLY MEMORANDUM IN SUPPORT OF PFIZER INC.'S MOTION TO COMPEL  
PRODUCTION OF DOCUMENTS FROM NON-PARTIES  
THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION  
AND THE ARCHIVES OF INTERNAL MEDICINE**

Pfizer Inc. (“Pfizer”) submits this reply memorandum in further support of its motion to compel the *Journal of the American Medical Association* (“JAMA”) and the *Archives of Internal Medicine* (“AIM”) to produce documents and states as follows:

**INTRODUCTION**

Pfizer subpoenaed documents from JAMA and AIM (collectively, “the Journals”), which are likely to lead to the discovery of admissible evidence in the underlying products liability Multi-District Litigation (“products liability MDL”). The Journals have refused to produce any documents other than copies of published articles, giving rise to this discovery dispute. During the parties’ extensive meet-and-confer over a period of six months, the Journals claimed privileges that are not applicable, some of which they have now abandoned.

In response to Pfizer’s Motion to Compel, the Journals argue that (1) the documents Pfizer seeks are not relevant or likely to lead to the discovery of relevant evidence; (2) the

Medical Studies Act and reporter's privileges protect the sought after documents from disclosure; and (3) the Journals provided a proper privilege log and have not waived any of their privilege claims. These arguments lack merit.

The Journals should be ordered to comply with the subpoenas for the following reasons: (1) the subpoenaed documents are potentially relevant to the products liability MDL, and are, therefore, reasonably calculated to lead to the discovery of admissible evidence; (2) the Journals waived any privilege claims because they failed to provide a privilege log; (3) the Medical Studies Act does not apply to the Journals; and (4) the reporter's privilege does not protect the subpoenaed documents. Accordingly, the Court should grant Pfizer's Motion to Compel and order the Journals to produce all documents concerning Bextra® and Celebrex®, including redacted peer-review comments, manuscripts submitted to the Journals, and documents regarding the decision to publish or not to publish any manuscripts.

## **ARGUMENT**

### **I. The Subpoena Seeks Documents Relevant To Numerous Products Liability Cases.**

The Journals' argue they are not obligated to produce documents because it believes they lack "sufficient probative value" to the claims Pfizer faces in the underlying cases. The Journals contend that the underlying cases are "consumer fraud and unjust enrichment, not strict liability or design defect" Cases. (Opp'n at 13; *see id.* at 2.)

The Journals' understanding is incorrect. Pfizer faces approximately 1,939 products liability cases in the MDL. The trial of the first products liability case is scheduled to begin on May 5, 2008 and includes allegations of negligence and strict liability based on failure to warn, design defect, and manufacturing defect claims. (*See* Ex. A, Pretrial Order No. 27: Scheduling Order for Initial MDL Trials; Ex. B, Compl.; Mot. to Compel at 2-4). In addition, Pfizer

explained in its Motion to Compel that the subpoenaed documents are reasonably likely to lead to the discovery of admissible evidence in the product liability cases because they relate to “study results, hypotheses and biological explanations and causal relationships regarding Celebrex® and Bextra®; Pfizer’s involvement in scientific publications; and Pfizer’s responses to scientific publications,” all of which are at issue in the products liability MDL. (Mot. to Compel at 8-9.) The Journals do not dispute this; they state in their opposition that the documents in their possession pertain to the “safety” of Bextra® and Celebrex®. (Opp’n at 1.)

Finally, the Journals’ express a concern that production of peer-review documents will discourage physicians from participating in the peer-review process. Pfizer has no desire to disturb the integrity of the peer-review process and is mindful and respectful of the important role that medical journals play in the protecting the public health. For this reason, Pfizer explained during the meet-and-confer process that it is seeking the content of peer review comments only, not the identity of any physician or scientist who participated in the Journals’ peer-review of the subject articles and manuscripts.

## **II. The Journals’ Failure to Produce an Adequate Privilege Log Constitutes a Waiver of any Privilege.**

The Journals contend that providing only a list of privileges as their “privilege log” satisfies their responsibilities under the Federal Rules of Civil Procedure. This is not correct. As we explained in our motion, Rules 26(b)(5)(A) and 45(d)(5)(A) state that a person withholding a document on a claim of privilege must: “(i) expressly make the claim; and (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, *will enable the parties to assess the claim.*” FED. R. Civ. P. 26(b)(5)(A)(i)-(ii); 45(d)(5)(A)(i)-(ii) (emphasis added); *see also* Mot. to Compel at 13-14. Over a period of four months Pfizer repeatedly requested that the Journals produce a

privilege log. (See Exs. G, H and I to Mot. to Compel.) The Journals' refused, and as a result they have waived their claims. *See Smithkline Beecham Corp. v. Apotex Corp.*, 193 F.R.D. 530, 534 (N.D. Ill. 2000) (production of documents ordered for failure to produce privilege log); *In re Application for Subpoena to Kroll*, 224 F.R.D. 326, 328 (E.D.N.Y. 2004) (failure to produce a privilege log pursuant to Rule 45 constitutes waiver). Illinois law also makes clear that with respect to at least one of the Journals' claimed privileges, the Medical Studies Act, “[a] party's ‘mere assertion that the matter is confidential and privileged will not suffice.’” *Menoski v. Shih*, 612 N.E.2d 834, 836 (Ill. App. 1993). Illinois courts have “held that [parties asserting the MSA privilege] should [] support[] their claim of privilege either by producing the materials for an *in camera* inspection or by submitting affidavits setting forth facts sufficient to establish the applicability of the privilege to the particular documents.” *Id.* at 837 (citing *Ekstrom v. Temple*, 553 N.E.2d 424 (Ill. App. 1990)).

The Journals' response to Pfizer's subpoena is an example of why detailed privilege logs are required under the federal rules. The Journals originally refused to produce documents because they claimed they were protected by four privileges – the Medical Studies Act (“MSA”), the reporter's privilege, “the peer review process privilege,” and unspecified “ethical rules” and “obligations.” (See Ex. E to Mot. to Compel.) In their Opposition, however, they drop two of their claimed privileges and assert the Medical Studies Act and the reporter's privilege only. Despite having dropped half of their claimed privileges, they did not produce any of the documents allegedly withheld under those privileges.

Second, four months after initially asserting their privileges, the Journals described four broad categories of withheld documents (all categories of documents, which other scientific journals have produced to Pfizer in response to similar subpoenas), without making any effort to

link the categories of withheld documents to any particular privilege asserted.<sup>1</sup> (*See* Ex. J to Mot. to Compel.)

As a result, neither Pfizer nor the Court can assess either the validity of the asserted privileges or the volume of documents withheld. (*See* Exs. H to Pfizer's Mot. to Compel.)

The Journals claim that requiring them to prepare a detailed log would amount to a waiver in and of itself. (Ex. J. to Mot. to Compel; *see also* Opp'n at 12-13.) That is not the case. The Rules do not require a disclosure so detailed as to amount to waiver of the asserted privilege. The Rules simply require information sufficient to assess the validity of the asserted privilege. *See* FED. R. CIV. P. 26(b)(5)(A)(i)-(ii), 45(d)(5)(A)(i)-(ii). Civil litigants routinely manage to prepare logs that comply with the rules without waiving privileges and the Journals are no doubt capable of doing the same.

### **III. The Medical Studies Act Does Not Protect the Journals' Peer-Review of Third Party Manuscripts.**

The Journals argue that the Medical Studies Act ("MSA") applies to them, merely because they are affiliated with the American Medical Association ("AMA"). The Journals are wrong. Simply stated, the MSA does not apply to editors or publishers, regardless of the content they disseminate or their mission in doing so. As Pfizer explained in its motion, and as discussed in further detail below, the MSA only applies to documents of an accredited hospital's or medical staff's peer review committee, and which are used in the course of internal quality

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<sup>1</sup> The Journals described the broad categories as follows:

1. Correspondence to and from authors to JAMA editors throughout the editorial process of submission, consideration, revision, acceptance and publication.
  2. Correspondence to, from and among editors and peer reviewers throughout the editorial process.
  3. Authorship forms regarding, among other things, disclosures and representations by all co-authors regarding their role in the preparation of the manuscript, figures and tables, in the underlying research or clinical trial and any pertinent financial interest or affiliation, all for consideration by the editors in deciding whether and what to publish;
  4. Various versions of manuscripts, figures and tables from submission through editing to publication.
- (*See* Ex. J to Mot. to Compel.)

control or medical studies aimed at reducing morbidity or mortality or improving healthcare. *See* 735 ILL. COMP. STAT. ANN. 5/8-2101; *Grandi v. Shah*, 633 N.E.2d 894, 898 (Ill. App. 1994); *see also* Mot. to Compel at 11-12.

**A. *The Journals Are Not Protected Organizations Under the MSA.***

The Journals claim the MSA applies to them because they are affiliated with the American Medical Association (“AMA”). (Opp’n at 7-9.) Pfizer did not subpoena the AMA, however, it subpoenaed the Journals, and, in any event, the statute neither protects the AMA nor the Journals.

The Journals’ rely on *Niven v. Siqueira*, 487 N.E.2d 937 (Ill. 1985) for the proposition that medical societies such as the AMA are protected under the MSA. The Journals misread the case. *Niven* holds that an entity that was the “the sole accreditor of hospitals” is covered by the statute because the entity “will not accredit a hospital which does not allow it access to the very materials protected by the statute.” *Id.* at 942. As a result, the Court held that the MSA covered the credentialing agency as well because its work necessarily involved the review of “materials . . . gathered as part of a program designed to improve quality control and patient care.” *Id.* at 942.

The AMA is not analogous to the Joint Commission. The Journals have provided no evidence that they or the AMA are involved in a protected activity, i.e., studies for the purpose of reducing morbidity or mortality at hospitals.

Even if the AMA were involved in activities protected under the statute, that protection does not necessarily extend to all AMA-related entities. The protections only apply to committees engaged in quality control at health care facilities or medical studies aimed at reducing morbidity or mortality or improving healthcare. *See* 735 ILL. COMP. STAT. ANN. 5/8-

2101; *Grandi v. Shah*, 633 N.E.2d 894, 898 (Ill. App. 1994). The Journals, on the other hand, are in the business of publishing manuscripts voluntarily submitted to them and generating revenue through the sale of advertisements and journal subscriptions. Their Editorial Counsel considers the Journals distinct from the AMA. *See Ex. E.* to Pfizer's Mot. to Compel ("While published by the AMA, these journals are part of a separate division of the AMA directed by the Editor-in-Chief of JAMA . . ."). Any committee of the Journals is engaged in assessing the worthiness of manuscripts for publication. These are not the type of peer-review committees for which the statute contemplates protection.

**B. *The Subpoenaed Documents are Not the Type the MSA Protects.***

Even though the Journals did not provide a privilege log, it is clear that none of the documents they are withholding are subject to the MSA.

Illinois courts interpret the MSA as requiring that any documents withheld actually belong to a committee "of a licensed or an accredited hospital or its medical staff." *Grandi v. Shah*, 633 N.E.2d 894, 898 (Ill. App. 1994); *Roach v. Springfield Clinic*, 623 N.E.2d 246, 250 (Ill. 1993) ("What the law actually protects is . . . information of 'committees of licensed or accredited hospitals or their medical staffs . . .'" (emphasis in original)). Pfizer's subpoenas seek documents related to the peer-review process. "Not every document which has some connection to a peer-review committee is subject to the privilege," however, and the privilege does not apply to actions taken as a result of the [peer review] process." *Menoski v. Shih*, 612 N.E.2d 834, 836 (Ill. App. 1993).

Specifically, categories 1 and 2 of the documents that the Journals are withholding relate to communications with editors, peer-reviewers and authors "throughout the editorial process," not to documents that relate to a medical study that the Journals conducted for the purpose of

reducing morbidity or mortality or for improving healthcare. Category 3 relates to authorship forms, which contains information provided by the authors that is not used in the course of manuscript review and bears no relation to the work of the reviewers and editors. *See* <http://jama.ama-assn.org/misc/ifora.dtl> (last accessed March 4, 2008); *see also Cukier v. Journal of the AMA*, 630 N.E.2d 1198, 1201 (Ill. App. 1994) (“Financial disclosure information is not provided to peer reviewers and the fact that an author has a financial interest in the subject area of his article does not preclude publication of said article.”). Category 4 relates to “various versions of manuscripts, figures and tables from submission through editing to publication.”

None of these categories describes documents that were used in the course of internal quality control or in the course of a medical study. As a result, the MSA does not apply and the documents must be produced.

#### **IV. The Reporter’s Privilege Does Not Protect The Subpoenaed Documents.**

The Journals claim the reporter’s privilege applies to the subpoenaed documents. In so doing, they insist on one had that they qualify for protection under the MSA as an “allied medical society,” yet, at the same time, argue they are a news medium and their editors and reviewers warrant the protection of the reporter’s privilege. The Journals cannot have it both ways. To argue both implicitly acknowledges that neither fits.

The language of the reporter’s privilege statute is plain: “No court may compel any person to disclose the source of any information obtained by a reporter . . .” 735 ILL. COMP. STAT. ANN. 5/8-901. “The objective of the privilege is ‘to preserve the autonomy of the press by allowing reporters to assure their sources of confidentiality, thereby permitting the public to receive complete, unfettered information.’” *Cukier v. Journal of the AMA*, 630 N.E.2d 1198, 1200 (Ill. App. 1994) (quoting *In re Subpoena Duces Tecum to Arya*, 589 N.E.2d 832, 834 (Ill.

App. 1992)); *People v. Palacio*, 607 N.E.2d 1375, 1383 (Ill. App. 1993) (“In Illinois, reporters have a statutory, qualified privilege that protects the anonymity of their sources, whether confidential or nonconfidential.”). As we also explained, we have repeatedly offered to accept documents redacted to protect the identity of the Journals’ sources. (See Pfizer’s Mot. to Compel at 10-11, and Ex. J thereto.) Moreover, the Journals’ production would be subject to an existing protective order, which, in combination with the redaction of sources completely undermines any reasonable argument concerning the Journals’ concerns of confidentiality. (See Ex. C, Protective Order.)

The Journals now argue that the content of peer review comments must remain secret, not just the identities of the reviewers. This misstates the plain language of the statute, assuming it applies, which protects the “source,” defined as “the person **or** means from or through which the news or information was obtained.” 735 ILL. COMP. STAT. ANN. 5/8-902(c) (emphasis added).

The Journals rely on *People v. Slover*, 753 N.E.2d 554 (Ill. App. 2001) for the proposition that content, as well as source, is protected under the reporter’s privilege. That case is distinguishable, however, because there the content and the sources were the same, namely, a photograph. The photographs in *Slover* were deemed a means of *gathering news*, which brought them within the definition of “source.” Here, Pfizer seeks neither “news” nor “sources;” it seeks only the content of scientific comments made on voluntarily submitted research articles.

Finally, because the reporters’ privilege does not apply here, the Journals’ request that we apply for a divestiture of the privilege is inapposite.

For these reasons, the reporter’s privilege does not apply to this matter and the court should compel the production of the subpoenaed materials.

### Conclusion

For the foregoing reasons, Pfizer respectfully requests that this Court grant its Motion to Compel and order JAMA and AIM to produce documents in accordance with the subpoenas within seven days from the date of the Order, and award Pfizer reasonable costs, including attorneys' fees.

Dated: March 7, 2008

Respectfully submitted,

**PFIZER INC.**

/s/ Matthew J. Sullivan

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**CERTIFICATE OF SERVICE**

I, Matthew J. Sullivan, attorney for Pfizer Inc. hereby certify that I have caused a copy of the foregoing to be served on the following counsel via the electronic filing system:

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on this March 7, 2008.

/s/ Matthew J. Sullivan  
Matthew J. Sullivan